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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,002	10/17/2001	Wayne M. Barnes	TKR 2050.1	6531
26263	7590	10/06/2003		
SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			EXAMINER FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1634	14
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/981,002	Applicant(s) BARNES, WAYNE M.	
	Examiner Jeffrey Fredman	Art Unit 1634	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6-13 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6-13 and 17-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status

The current application may potentially be involved in an interference. In order to ensure that the interference will be accepted by the BPAI, all examination issues must be completed. Therefore, the current action is intended to hopefully fully address the double patenting issues which remain, as well as a single prior art issue, so that upon a response being filed, these cases can either enter the interference proceedings or be allowed. With regard to the Klentaq1 issue below, if Applicant wishes to demonstrate that Klentaq1 is identical to some other described enzyme, Applicant is requested to simply provide a declaration under 1.132 explaining of what Klentaq1 is composed.

Priority

1. Applicant's claim for priority under 35 U.S.C. 120 to U.S. Patent 5,436,149, filed February 19, 1993 is acknowledged. However, the patent upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 23, 25, 28, 31, 33, 36 of this application. Each of these claims refers to Klentaq1, however, the parent patent application was wordsearched on EAST (a computer program with the full text of the patent) and no reference to Klentaq1 was found (though other Klentaq enzymes such as Klentaq-278 or Klentaq-291 were found). Since it is not clear, even from the current specification, what Klentaq1 is supposed to be (such as Klentaq-278), these claims are not given priority to U.S. Patent 5,436,149.

Double Patenting

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2. Claims 3, 4, 6-13, 17-22, 24, 26, 27, 29, 30, 32, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,410,277 in view of Kosak et al (U.S. Patent 5,413,924).

Claims 1-4 of U.S. Patent No. 6,410,277 teach a formulation of thermostable DNA polymerases comprising at least one thermostable DNA polymerase lacking 3'-5' exonuclease activity and at least one thermostable DNA polymerase exhibiting 3'-5' exonuclease activity. The claims further teach a kit for the synthesis of a polynucleotide, said kit comprising a first DNA polymerase, wherein said first polymerase possesses 3'-5' exonuclease activity and a second DNA polymerase, wherein said second polymerase lacks 3'-5' exonuclease activity. Lastly, the claims teach a kit according to claim 2, said kit further comprising DNA primers. (see claims 1, 2 and 4). Claim 3 teaches the method of use.

These claims do not teach the full list of equivalent enzymes including Taq, Pfu and Vent which are in the current claims.

Kozak teaches the equivalence of these enzymes was known in the prior art, stating "Many such enzymes can be used such as those from thermophilic organisms. For example, various RNA polymerases such as Q beta replicase from bacteriophage, among others, and DNA polymerases from *Thermophilus* sp. ("Taq"), *Thermococcus* sp. ("vent"), *Thermus* sp. ("Tth" and recombinant "rTth") and *Pyrococcus* sp. ("pfu"), as well as DNA ligases such as "ampligase", from Epicentre Technologies, and any

other enzymes from thermophilic microorganisms and invertebrates, including forms produced by recombinant DNA technology." (see column 4, lines 46-56).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the species of polymerases taught by Kozak as equivalent in the method of claims 1-4 of U.S. Patent No. 6,410,277 since an ordinary practitioner would have been motivated to use equivalent enzymes in the thermostable composition and kit of claims 1-4 of U.S. Patent No. 6,410,277 in order to permit use of a wider range of enzymes. Further, MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

3. Claims 23, 25, 28, 31, 33, 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,410,277 in view of Barnes (Proc. Natl. Acad. Sci. (1994) 91:2216-2220).

Claims 1-4 of U.S. Patent No. 6,410,277 teach a formulation of thermostable DNA polymerases comprising at least one thermostable DNA polymerase lacking 3'-5' exonuclease activity and at least one thermostable DNA polymerase exhibiting 3'-5' exonuclease activity. The claims further teach a kit for the synthesis of a polynucleotide, said kit comprising a first DNA polymerase, wherein said first

polymerase possesses 3'-5' exonuclease activity and a second DNA polymerase, wherein said second polymerase lacks 3'-5' exonuclease activity. Lastly, the claims teach a kit according to claim 2, said kit further comprising DNA primers. (see claims 1, 2 and 4). Claim 3 teaches the method of use.

These claims do not teach the use of Klentaq1.

Barnes teaches the use of Klentaq1 as an equivalent of Taq (see page 2216, column 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the species of polymerases taught by Barnes as equivalent in the method of claims 1-4 of U.S. Patent No. 6,410,277 since an ordinary practitioner would have been motivated to use equivalent enzymes in the thermostable composition and kit of claims 1-4 of U.S. Patent No. 6,410,277 in order to permit use of a wider range of enzymes. Further, MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

4. Claims 3, 4, 6-13, 17-19, 29, 30, 32, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-16 of U.S. Patent No. 5,436,149. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because Claims 6-16 of U.S. Patent No. 5,436,149 teach a formulation of thermostable DNA polymerases comprising at least one thermostable DNA polymerase lacking 3'-exonuclease activity and at least one thermostable DNA polymerase exhibiting 3'-exonuclease activity, wherein the DNA polymerases are present in a ratio of from about 4 units to about 2000 units of the DNA polymerase lacking 3'-exonuclease activity to 1 unit of the DNA polymerase exhibiting 3'-exonuclease activity. The claims further teach a formulation of thermostable DNA polymerases as set forth in claim 6 wherein the at least one thermostable DNA polymerase lacking 3'-exonuclease activity is a DNA polymerase comprising substantially the same amino acid sequence as that of *Thermus aquaticus* DNA polymerase, excluding the N-terminal 280 amino acid residues of *Thermus aquaticus* DNA polymerase. Claims 6-16 further teach a formulation of thermostable DNA polymerases as set forth in claim 6 wherein the at least one thermostable DNA polymerase exhibiting 3'-exonuclease activity is selected from the group consisting of Pfu polymerase from *Pyrococcus furiosus*, the Vent DNA polymerase from *Thermococcus litoralis*, a variant of the Pfu DNA polymerase wherein the DNA polymerase activity of said Pfu DNA polymerase has been diminished or inactivated, or a variant of the Vent DNA polymerase wherein the DNA polymerase activity of said Vent DNA polymerase has been diminished or inactivated.

5. Claims 3, 4, 6-13, 17-22, 24, 26, 27, 29, 30, 32, 34 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 08/483,535.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims both teach formulations of two DNA polymerases, including vent, Taq, PFU and Klentaq, as well as methods of using these polymerases for amplification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 23, 25, 28, 31, 33, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes (Proc. Natl. Acad. Sci. (1994) 91:2216-2220).


Barnes teaches a method for amplifying a polynucleotide sequence by mixing the sequence with a primer and KlenTaq1 and a second polymerase like Deep vent or vent or pfu as well as the product compositions themselves (see page 2218, column 2). The word "kit" is not given patentable weight to distinguish from the product because no structural limitations are imposed by the term in this claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
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